UNITED STATES DISTRICT COURT

DISTRICT OF DELAWARE

ARTHROCARE CORPORATION, Plaintiff, v. SMITH & NEPHEW, INC., Defendant.	Civil Action No. 01-504 SLR

PLAINTIFF ARTHROCARE CORPORATION'S SUPPLEMENTAL OBJECTIONS AND RESPONSES TO DEFENDANT SMITH & NEPHEW'S INTERROGATORIES (NOS. 20 & 21)

Pursuant to Fed. R. Civ. P. 33 and this Court's Local Rules, ArthroCare Corporation ("ArthroCare") hereby objects and responds to defendant Smith & Nephew, Inc.'s ("Smith & Nephew's") Fourth Set of Interrogatories as follows:

GENERAL OBJECTIONS

A. ArthroCare objects to each of Smith & Nephew's interrogatories to the extent it seeks information protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity from production.

B. ArthroCare objects to each of Smith & Nephew's interrogatories to the extent it seeks trade secrets or other confidential or proprietary information of ArthroCare or third parties.

C. According to Smith & Nephew's Fourth Set of Interrogatories, "the definitions and instructions in Defendant Smith & Nephew, Inc.'s First Set of Interrogatories to Plaintiff (Nos. 1-14) are incorporated herein by reference." As such, ArthroCare incorporates herein and realleges its General Objections to Defendant Smith & Nephew, Inc.'s First, Second, and Third Sets of Interrogatories to Plaintiff (Nos. 1-14, 15-16 and 17-18) as if they were set forth fully herein.

D. ArthroCare objects to each of Smith & Nephew's interrogatories to the extent it seeks to impose obligations beyond or inconsistent with those imposed by the Federal Rules of Civil Procedure, the Court's Local Rules, or orders of the Court.

E. Inadvertent disclosure of privileged information by ArthroCare shall not constitute the waiver of any applicable privilege or doctrine.

F. ArthroCare's discovery and investigation in connection with this action are continuing. As a result, ArthroCare's responses are limited to documents reviewed and information considered to date, and are given without prejudice to ArthroCare's right to amend or supplement its responses after considering additional or different documents or information obtained and reviewed through further discovery or investigation.

INTERROGATORY RESPONSES

INTERROGATORY NO. 20:

State in detail the complete factual basis for any contention that the claims of the patents-in-suit are valid, including without limitation the Identity of all persons with knowledge of such facts, and including the Identity of all documents that relate to, support, conflict with or contradict the validity of the claims of the patents-in-suit.

RESPONSE TO INTERROGATORY NO. 20:

In addition to its General Objections, ArthroCare objects to this interrogatory on the grounds that Smith & Nephew has failed to set forth in detail the bases for its contentions that the patents-in-suit are invalid, despite being given additional time by the Court to supplement its contentions and despite the fact that ArthroCare served detailed infringement claim charts identifying not only where every limitation of the patents-in-suit can be found in the accused devices, but also identifying exemplary documents supporting those contentions. The deficiencies in Smith & Nephew's supplemental responses include, among other things, the failure to identify where any of the limitations of the patents-in-suit can be found among any one of the 73 references Smith & Nephew cites, the failure to explain how and why a person skilled in the art would have been motivated to combine any specific reference with any other specific reference, and the failure to state any basis for its claims that the patents-in-suit are invalid for indefiniteness or incorrect inventorship. ArthroCare further objects that this interrogatory is premature because the Court allowed ArthroCare until two weeks after Smith & Nephew served its supplemental contention responses to provide ArthroCare's supplemental responses on issues for which ArthroCare does not bear the burden of proof.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 20:

Please see Exhibit A.

INTERROGATORY NO. 21:

If you contend that Smith & Nephew's contentions concerning invalidity of the patents-in-suit are incorrect in any way, state in detail the complete factual basis for your contention and Identify all individuals with knowledge of facts relating to your contention and Identify all documents and things relating to your contention.

RESPONSE TO INTERROGATORY NO. 21:

In addition to its General Objections, ArthroCare objects to this interrogatory on the grounds that Smith & Nephew has failed to set forth in detail the bases for its contentions that the patents-in-suit are invalid, despite being given additional time by the Court to supplement its

contentions and despite the fact that ArthroCare served detailed infringement claim charts identifying not only where every limitation of the patents-in-suit can be found in the accused devices, but also identifying exemplary documents supporting those contentions. The deficiencies in Smith & Nephew's supplemental responses include, among other things, the failure to identify where any of the limitations of the patents-in-suit can be found among any one of the 73 references Smith & Nephew cites, the failure to explain how and why a person skilled in the art would have been motivated to combine any specific reference with any other specific reference, and the failure to state any basis for its claims that the patents-in-suit are invalid for indefiniteness or incorrect inventorship. ArthroCare further objects that this interrogatory is premature because the Court allowed ArthroCare until two weeks after Smith & Nephew served its supplemental contention responses to provide ArthroCare's supplemental responses on issues for which ArthroCare does not bear the burden of proof.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 21:

Please see Exhibit A.

Dated: October 15, 2002

WEIL, GOTSHAL, & MANGES LLP

By: _____
Perry Clark
Attorneys for Plaintiff
ARTHROCARE CORPORATION

DECLARATION OF SERVICE

I am a citizen of the United States, more than 18 years old, and not a party to this action. My place of employment and business address is 201 Redwood Shores Parkway, Redwood Shores, CA 94065. On October 14, 2002, I caused a copy of **PLAINTIFF ARTHROCARE CORPORATION'S SUPPLEMENTAL OBJECTIONS AND RESPONSES TO DEFENDANT SMITH & NEPHEW'S INTERROGATORIES (NOS. 20 & 21)** to be served on DEFENDANT Smith & Nephew, Inc. as follows:

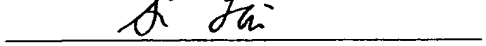
[ ] **BY MAIL** I am readily familiar with the business practice at my place of business for collection and processing of correspondence for mailing with the United States Postal Service. Correspondence so collected and processed is deposited with the United States Postal Service. Correspondence so collected and processed is deposited with the United States Postal Service that same day in the ordinary course of business. The above document was placed in a sealed envelope with first-class postage thereon fully prepaid, and placed for collection and mailing on that date following ordinary business practice.

[X] **BY FACSIMILE** The facsimile machine used to serve the above document on said party or parties produced a record showing that the facsimile transmission was completed successfully.

[ ] **BY OVERNIGHT COURIER SERVICE** I am readily familiar with the business practice at my place of business for collection and processing of correspondence for deposit with an overnight delivery service. Correspondence placed for collection and processing is either delivered to a courier or driver authorized by said overnight delivery service to receive documents or deposited by an employee or agent of this firm in a box or other facility regularly maintained by said overnight delivery service that same day in the ordinary course of business.

[ ] **BY HAND DELIVERY** I caused said documents to be hand delivered to the parties designated below by delivering said copies thereof to a person over the age of eighteen (18) years and not a party to this action.

Executed on October 14, 2002 at Redwood Shores, California. I declare under penalty of perjury that the foregoing is true and correct.



DECLARATION OF SERVICE

I am a citizen of the United States, more than 18 years old, and not a party to this action. My place of employment and business address is 201 Redwood Shores Parkway, Redwood Shores, California, 94065-1175. On October 15, 2002, I caused a copy of **PLAINTIFF ARTHROCARE CORPORATION'S SUPPLEMENTAL OBJECTIONS AND RESPONSES TO DEFENDANT SMITH & NEPHEW'S INTERROGATORIES (NOS. 20 & 21)** to be served on DEFENDANT Smith & Nephew, Inc. as follows:

[X] BY MAIL I am readily familiar with the business practice at my place of business for collection and processing of correspondence for mailing with the United States Postal Service. In the ordinary course of business, correspondence so collected and processed is deposited with the United States Postal Service that same day with first-class postage thereon fully prepaid. On the above-referenced date, I placed the above document(s) in a sealed envelope addressed to the person(s) identified below and placed the envelope for collection and mailing following ordinary business practice.

[ ] BY FACSIMILE I am readily familiar with the business practice at my place of business for collection and processing of documents for transmission by facsimile. In the ordinary course of business, documents are collected and transmitted by facsimile using a facsimile machine that produces a record showing whether the facsimile transmission was completed successfully. On the above-referenced date, I delivered the above document(s) to the persons responsible for transmitting documents by facsimile following ordinary business practice. I have attached to the original papers being filed with the Court a copy of the transmission report confirming that transmission was successful. [Note: declaration to be executed only after receipt and attachment of transmission report]

[ ] BY OVERNIGHT COURIER SERVICE I am readily familiar with the business practice at my place of business for collection and processing of correspondence for deposit with an overnight delivery service. Correspondence placed for collection and processing

is either delivered to a courier or driver authorized by said overnight delivery service to receive documents or deposited by an employee or agent of this firm in a box or other facility regularly maintained by said overnight delivery service that same day in the ordinary course of business. On the above-referenced date, I sealed the above document(s) in an envelope or package designated by the courier service and addressed to the person(s) identified below, with payment of next day delivery fees provided for, and delivered the envelope/package to the office personnel responsible for delivering documents to overnight courier services following ordinary business practice.

Keith Walter
William Marsden
Fish & Richardson P.C.
919 North Market Street, Suite 1100
P.O. Box 1114
Wilmington, DE 19899-1114

Kurtis MacFerrin
FISH & RICHARDSON P.C.
500 Arguello Street
Suite 500
Redwood City, CA 94063-1526

Mark J. Hebert
Fish & Richardson P.C.
225 Franklin Street
Boston, Massachusetts 02110-2804

Executed on October 15, 2002 at Redwood Shores, California. I declare under penalty of perjury that the foregoing is true and correct.

Carolanna Lance-White

Exhibit A

ArthroCare's Preliminary Validity Contentions
***ArthroCare v. Smith & Nephew*, 01-0504 SLR**

I. Anticipation

References 8 and 15[1]: Neither U.S. Patent No. 4,166,198 to Roos (the "Roos '198 Patent"), which was disclosed during the prosecution of the '592 patent-in-suit, nor the article by E. Elsasser and E. Roos entitled "Concerning an Instrument for Transurethral Resection Without Leakage of Current" (the "Roos Article"), discloses or renders obvious any of the claimed inventions. The Roos '198 Patent and the Roos Article describe the same devices, which are designed to cut tissue during transurethral resection procedures.

The Roos '198 Patent never describes the use of "electrically conductive fluid" during electrosurgery. The Roos '198 Patent only discloses the use of an unspecified "washing liquid" that flows through the endoscope that houses the treatment and neutral electrodes. See Roos '198 Patent at 4:51-57, Fig. 1. The Roos '198 Patent does not state that the "washing liquid" that is supplied to the region of the surgical site is electrically conductive fluid. This omission is significant, because numerous non-conductive washing liquids, such as distilled water, glycine, sorbitol, and the like, have been used in electrosurgery and are still in use today. See, e.g., U.S. Patent No. 4,936,301 to Rexroth, et al. at 1:62-64 and 2:4-7.

In fact, the Roos '198 specification makes clear that the "washing liquid" delivered to the surgical site in the Roos '198 Patent is not electrically conductive. The Roos '198 Patent states at column 6, lines 51-53 that "the neutral electrode 11 in the form

[1] "Reference __" refers to the reference number set forth in Smith & Nephew's October 9, 2002 invalidity contentions.

of a steel band rests on the tissue in large area form, so that good electrical contact is ensured." If the "washing liquid" were electrically conductive, there would be no need for the neutral electrode to rest on the tissue in large area form to ensure good electrical contact: electrical contact between the neutral electrode and the cutting electrode would be ensured by the "washing liquid" itself. The statement in the Roos '198 Patent that tissue contact with the neutral electrode is needed to ensure electrical contact plainly shows that the "washing liquid" described in the Roos '198 Patent could not have been electrically conductive.

A later-issued patent to the same named inventor, U.S. Patent No. 4,706,667 ("the Roos '667 Patent") to Roos, demonstrates unequivocally that the "washing liquid" disclosed in the Roos '198 Patent was not electrically conductive. The Roos '198 Patent claims priority to German Patent Application No. 2521719 ("German Patent Application"). The Roos '667 Patent explains at column 1 lines 14-29 that the device described in the German Patent Application (and thus in the Roos '198 Patent) did not work to cut tissue because the medium in contact with the electrodes was not electrically conductive:

> In a known electro-surgical high frequency cutting instrument of this kind (DE-OS No. 25 21 719) the neutral electrode is admittedly arranged in the immediate vicinity of the cutting electrode, it is however so separated from the tissue by a plastic cover, or by its arrangement in an endoscope, that it can only enter into electrical contact with the cutting electrode electrolytically via the secretion which is present during the cutting process. As a result, it is difficult to maintain the current intensity required for trouble free cutting in a required precisely defined manner at the cutting electrode. Thus, if the power setting at the r.f. generator is too high, burns can result or, if the power setting is too low, then a poor cut or indeed injury occurs because the tissue to be cut sticks to the cutting electrode as a result of coagulation processes.

According to the Roos '667 Patent, the device disclosed in the parent application to the Roos '198 Patent (and thus in the Roos '198 Patent itself) did not work because there was insufficient electrical contact between the neutral and cutting electrodes to cut tissue, even though the electrodes were in the "immediate vicinity" of one another. If the Roos '198 Patent had delivered electrically conducting fluid to the tissue site, such as isotonic saline, then the Roos '667 Patent surely would not have stated, as it did, that the cutting and neutral electrodes "only enter into electrical contact" with each other "via the secretion which is present during the cutting process." If Roos '198 had delivered electrically conducting fluid to the tissue site, there would have been an electrical connection between the cutting and neutral electrodes by virtue of the electrically conducting fluid itself, regardless of whether bodily secretions were present. Plainly, Roos '198 used non-conducting "washing liquid" and attempted to rely on bodily secretions from the cutting process to make the non-conductive "washing liquid" more conductive. According to the Roos '667 Patent, these secretions did not make the non-conductive "washing liquid" electrically conductive.

Significantly, the Roos '667 Patent did not solve the electrical contact problem described in the Roos '198 Patent by introducing electrically conducting fluid to the tissue site. Rather, the Roos '667 Patent solved the problem of poor conductivity by disclosing a device in which both the cutting and neutral electrodes were in physical contact with the tissue so that current could flow from the cutting electrode, through the tissue, and to a return electrode, not through electrically conducting fluid:

> The instrument is first of all placed in accordance with FIG. 1 onto the tissue 16 which is to be separated by means of a cut, with a concave ring-like contact surface 14 being formed between the tissue 16 and the neutral electrode 11 and with a very small funnel-like contact surface 15 being

> formed between the tip of the cutting electrode 12 and the tissue 16. If the r.f. generator is now switched on then an r.f. current indicated by the current lines 28 flows between the cutting electrode 12 and the neutral electrode 11.

Because the Roos '198 Patent does not disclose or enable operation in an electrically conductive fluid, it cannot anticipate or render obvious claims containing that limitation.

Neither the Roos Article nor the Roos '198 Patent discloses an insulating member circumscribing a return electrode, and Smith & Nephew does not contend that they do. Moreover, neither reference discloses that the frequency applied between a return electrode and the electrode terminal is in the range of about 20 kHz and 20 Mhz, and Smith & Nephew does not contend that they do. In addition, neither reference discloses that the voltage applied between the electrode terminal and a return electrode is in the range from 10 volts (RMS) to 1000 volts (RMS), and Smith & Nephew does not contend that they do.

Neither the Roos Article nor the Roos '198 Patent discloses a high frequency voltage sufficient to vaporize the fluid over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer. Moreover, neither reference discloses that at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum. In addition, neither reference discloses that the voltage applied is at least 200 volts peak to peak or that it is in the range from about 500 to 1400 volts peak to peak, and Smith & Nephew does not contend that they do. Neither reference discloses that the distance between the proximal portion of the electrode terminal and most distal portion of a return electrode is in the range from about 0.5 to 10 mm, and Smith & Nephew does not contend that they

do. Moreover, neither reference discloses that the liquid phase of the fluid has a conductivity greater than 2 mS/cm nor that the fluid comprises isotonic saline.

Neither the Roos Article nor the Roos '198 Patent discloses ablation of tissue. In addition, neither reference discloses vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal. Moreover, neither reference discloses the discharge of photons to the target site in contact with a vapor layer, and Smith & Nephew does not contend that they do. Neither reference discloses that the electrode terminal has a contact surface area in the range of about 0.25 mm^2 to 50 mm^2, and Smith & Nephew does not contend that they do. In addition, neither reference discloses that the electrode terminal is positioned between 0.02 to 2.0 mm from the target site, and Smith & Nephew does not contend that they do. Moreover, neither reference discloses evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal, and Smith & Nephew does not contend that they do.

Neither the Roos Article nor the Roos '198 Patent discloses that an electrically conductive fluid completes the conduction path between the electrode terminal and a return electrode. In addition, neither reference discloses that an electrical current flows from the active electrode, through the electrically conductive fluid, and to a return electrode.

Reference 10: U.S. Patent 3,970,088 to Morrison ("Morrison '088 Patent") does not disclose or render obvious any of the claimed inventions. There is no teaching or suggestion in the Morrison '088 Patent that electrically conductive fluid creates a current flow path between the two electrodes, and Smith & Nephew does not

contend that it does. To the contrary, the Morrison '088 Patent teaches away from such a path, because it states that both electrodes are brought into contact with the tissue to be treated and that current flows through the tissue between the electrodes, as opposed to through an electrically conductive fluid, or that there is an arc across a gap between the active electrode and the tissue (column 6 lines 29-34, column 7 lines 59-62, and column 9 lines 1-3). The Morrison '088 Patent also teaches that both of the electrodes are designed to have a tissue a effect, and as such this reference does not disclose a return electrode (column 9 lines 33-36, column 10 lines 41-46).

The Morrison '088 Patent does not disclose that the frequency applied between a return electrode and the electrode terminal is in the range of about 20 kHz and 20 Mhz, and Smith & Nephew does not contend that it does. The Morrison '088 Patent does not disclose that a return electrode is spaced from the electrode terminal to minimize contact between a return electrode and the patient's tissue because a return electrode is designed to be in contact with the tissue. In addition, the Morrison '088 Patent does not disclose that the voltage applied between the electrode terminal and a return electrode is in the range from 10 volts (RMS) to 1000 volts (RMS), and Smith & Nephew does not contend that it does. Smith & Nephew also does not contend that this reference discloses a device for use on a target site selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

The Morrison '088 Patent does not disclose a high frequency voltage sufficient to vaporize the fluid over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

Moreover, the Morrison '088 Patent does not disclose that at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum. In addition, the Morrison '088 Patent does not disclose that the voltage applied is at least 200 volts peak to peak or that it is in the range from about 500 to 1400 volts peak to peak, and Smith & Nephew does not contend that it does. The Morrison '088 Patent does not disclose that the distance between the proximal portion of the electrode terminal and the most distal portion of a return electrode is in the range from about 0.5 to 10 mm, and Smith & Nephew does not contend that it does. Moreover, the Morrison '088 Patent does not disclose that the liquid phase of the fluid has a conductivity greater than 2 mS/cm nor that the fluid comprises isotonic saline, and Smith & Nephew does not contend that it does.

The Morrison '088 Patent does not disclose ablation of tissue, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal. Moreover, this reference does not disclose the discharge of photons to the target site in contact with a vapor layer. The Morrison '088 Patent does not disclose that the electrode terminal has a contact surface area in the range of about 0.25 mm^2 to 50 mm^2, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose that the electrode terminal is positioned between 0.02 to 2.0 mm from the target site, and Smith & Nephew does not contend that it does. Moreover, the Morrison '088 Patent does not disclose evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal, and Smith & Nephew does not contend that it does.

The Morrison '088 Patent does not disclose, as discussed above, a return electrode that is not in contact with the body structure, and Smith & Nephew does not contend that it does. The Morrison '088 Patent also does not disclose that an active electrode, return electrode, target site, and tissue structure are immersed in electrically conducting fluid, and Smith & Nephew does not contend that it does. The Morrison '088 Patent also does not disclose delivering electrically conductive fluid to the target site, and Smith & Nephew does not contend that it does. The Morrison '088 Patent also does not disclose that an electrically conductive fluid completes the conduction path between the electrode terminal and a return electrode, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose that an electrical current flows from the active electrode, through the electrically conductive fluid, and to a return electrode.

Reference 22: U.S. Patent No. 4,326,529 to Doss et al. ("Doss '529 Patent"), which was cited to the Examiner during the prosecution of the patents-in-suit, does not disclose or render obvious any of the claimed inventions. Doss '529 describes a monopolar device for heating the corneal stroma, a portion of the cornea that is located below the surface of the cornea (column 2, lines 28-35, column 3, lines 58-62). The device described in Doss '529 Patent uses a high pressure flow of saline to keep the corneal surface cool during treatment. The Doss '529 device uses what it describes as a "circulating saline electrode," in which circulating saline confined within a tube forms an integral portion of the active electrode (column 4, line 41, column 5, lines 54-60, Figs. 2-5). The current flows from the circulating saline electrode through the patient's body to reach a return electrode, which is placed on the back of the patient's head or neck. Nothing in Doss '529 suggests placing a return electrode in contact with electrically

conducting fluid or using electrically conducting fluid to generate a current flow path between the active and return electrodes of the device.

The Doss '529 Patent does not disclose that a return electrode forms a portion of the shaft of the electrosurgical probe, and Smith & Nephew does not contend that it does. The Doss '529 Patent also does not disclose an insulating member circumscribing a return electrode nor a return electrode spaced from the electrode terminal to minimize direct contact between a return electrode and the patient's tissue, and Smith & Nephew does not contend that it does. Smith & Nephew also does not contend that this reference discloses a device for use on a target site selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body. In addition, the Doss '529 Patent does not disclose that the frequency applied between a return electrode and the electrode terminal is in the range of about 20 kHz and 20 Mhz, and Smith & Nephew does not contend that it does.

The Doss '529 Patent does not disclose a high frequency voltage sufficient to vaporize the fluid over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer, and Smith & Nephew does not contend that it does. Moreover, the Doss '529 Patent does not disclose that at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum, and Smith & Nephew does not contend that it does. In addition, the Doss '529 Patent does not disclose that the voltage applied is at least 200 volts peak to peak or that it is in the range from about 500 to 1400 volts peak to peak, and Smith & Nephew does not contend that it does. The Doss '529 Patent does not disclose

that the distance between the proximal portion of the electrode terminal and most distal portion of a return electrode is in the range from about 0.5 to 10 mm, and Smith & Nephew does not contend that it does.

The Doss '529 Patent does not disclose ablation of tissue, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal, and Smith & Nephew does not contend that it does. Moreover, this reference does not disclose the discharge of photons to the target site in contact with a vapor layer, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose that the electrode terminal is positioned between 0.02 to 2.0 mm from the target site, and Smith & Nephew does not contend that it does. Moreover, the Doss '529 Patent does not disclose evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal, and Smith & Nephew does not contend that it does.

The Doss '529 Patent does not disclose, as discussed above, a return electrode that is not in contact with the body structure, and Smith & Nephew does not contend that it does. The Doss '529 Patent also does not disclose that a return electrode is positioned within electrically conducting fluid. The Doss '529 Patent also does not disclose that an electrically conductive fluid completes the conduction path between the electrode terminal and a return electrode, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose that an electrical current flows from the active electrode, through the electrically conductive fluid, and to a return electrode.

Reference 23: U.S. Patent No. 4,381,007 to Doss ("Doss '007 Patent"), which was cited to the Examiner during the prosecution of the patents-in-suit, does not disclose or render obvious any of the claimed inventions. Doss '007 Patent describes a device for heating corneal stroma using biactive or quadrapole electrodes and saline flow to cool the corneal surface. The biactive devices have two tubular electrodes, arranged adjacent to each other or concentrically (column 4, lines 28-29, column 5, lines 27-31, Figs. 1, 2, 7, 8). The quadrapole electrode is composed of three separate electrodes, with the center electrode counting as two poles because it carries twice as much current as the other two (column 5, lines 19-24, Figs. 5, 6). Neither the biactive nor the quadrapole device has a return electrode as recited in the asserted claims of the patents-in-suit. The absence of a "return" electrode is important to the function of the devices claimed in the Doss '007 Patent because those devices are intended to generate a tissue effect between the electrodes deep in the tissue rather than at one electrode or the other.

The Doss '007 Patent does not disclose a return electrode spaced from the electrode terminal to minimize direct contact between a return electrode and the patient's tissue. Smith & Nephew also does not contend that this reference discloses a device for use on a target site selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

The Doss '007 Patent does not disclose a high frequency voltage sufficient to vaporize the fluid over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer, and Smith & Nephew does not contend that it does. Moreover, the Doss '007 Patent does not disclose

that at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum, and Smith & Nephew does not contend that it does. In addition, the Doss '007 Patent does not disclose that the voltage applied is in the range from about 500 to 1400 volts peak to peak. The Doss '007 Patent does not disclose that the distance between the proximal portion of the electrode terminal and most distal portion of a return electrode is in the range from about 0.5 to 10 mm, and Smith & Nephew does not contend that it does.

The Doss '007 Patent does not disclose ablation of tissue, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal, and Smith & Nephew does not contend that it does. Moreover, this reference does not disclose the discharge of photons to the target site in contact with a vapor layer, and Smith & Nephew does not contend that it does. The Doss '007 Patent also does not disclose that the electrode terminal has a contact surface area in the range of about 0.25 mm^2 to 50 mm^2, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose that the electrode terminal is positioned between 0.02 to 2.0 mm from the target site, and Smith & Nephew does not contend that it does. Moreover, the Doss '007 Patent does not disclose evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal, and Smith & Nephew does not contend that it does.

References 26 & 29: The two articles by Slager et al., entitled "Vaporization of Atherosclerotic Plaques By Spark Erosion" ("Slager et al. 1985") and "Spark Erosion Of Arteriosclerotic Plaques" ("Slager et al. 1987"), do not disclose or

render obvious any of the claimed inventions. The active and return electrodes of the device are placed in contact with the tissue. Slager et al. 1985 at page 1387; Slager et al. 1987 at page 68, 71. The current flows from the active electrode, through the tissue and to a return electrode, and as such, neither reference discloses a current flow path between the active and return electrode through an electrically conducting fluid. In addition, neither reference discloses delivering electrically conducting fluid to a target site on a patient's body.

Neither of these references discloses that a return electrode forms a portion of the shaft of the electrosurgical probe nor that there is an insulating member circumscribing a return electrode. Neither reference discloses a return electrode that is spaced from the electrode terminal to minimize contact between a return electrode and the patient's tissue.

Neither reference disclose that the distance between the proximal portion of the electrode terminal and most distal portion of a return electrode is in the range from about 0.5 to 10 mm.

In addition, these references do not disclose the discharge of photons to the target site in contact with a vapor layer. In addition, neither reference discloses that the electrode terminal is positioned between 0.02 to 2.0 mm from the target site. Moreover, neither reference discloses evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal, and Smith & Nephew does not contend that it does.

Reference 31: U.S. Patent No. 4,674,499 to Pao, which was disclosed during the prosecution of the patents-in-suit, neither discloses nor renders obvious any of

the asserted claims of the ArthroCare patents-in-suit. There is no teaching or suggestion in the Pao '499 Patent that electrically conductive fluid creates a current flow path between the two electrodes. To the contrary, the Pao '499 Patent teaches away from such a path, because it states that both electrodes are brought into contact with the tissue to be treated and that current flows through the tissue between the electrodes -- not through electrically conductive fluid (column 3 lines 11-15 and column 9 lines 58-63). The Pao '499 Patent does not teach that fluid is used for current conduction, but instead for the different purposes of removing blood, other fluid, and debris from the surgical site (column 3 lines 2-10 and column 8 line 66 to column 9 line 2). The Pao '499 Patent also does not disclose a return electrode which is designed to reduce tissue effect because both electrodes are designed to cause a tissue effect in a region between the two electrodes.

The Pao '499 Patent does not disclose that the frequency applied between a return electrode and the electrode terminal is in the range of about 20 kHz and 20 Mhz, and Smith & Nephew does not contend that it does. The Pao '499 Patent does not disclose that a return electrode is spaced from the electrode terminal to minimize contact between a return electrode and the patient's tissue because a return electrode is designed to be in contact with the tissue. In addition, the Pao '499 Patent does not disclose that the voltage applied between the electrode terminal and a return electrode is in the range from 10 volts (RMS) to 1000 volts (RMS), and Smith & Nephew does not contend that it does.

The Pao '499 Patent does not disclose a high frequency voltage sufficient to vaporize the fluid over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer. Moreover, the Pao '499 Patent does not disclose that at least a portion of the energy induced is in the form of

photons having a wavelength in the ultraviolet spectrum. In addition, the Pao '499 Patent does not disclose that the voltage applied is at least 200 volts peak to peak or that it is in the range from about 500 to 1400 volts peak to peak, and Smith & Nephew does not contend that it does. The Pao '499 Patent does not disclose that the distance between the proximal portion of the electrode terminal and most distal portion of a return electrode is in the range from about 0.5 to 10 mm. Moreover, the Pao '499 Patent does not disclose that the liquid phase of the fluid has a conductivity greater than 2 mS/cm.

The Pao '499 Patent does not disclose ablation of tissue, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal. Moreover, this reference does not disclose the discharge of photons to the target site in contact with a vapor layer. In addition, this reference does not disclose that the electrode terminal is positioned between 0.02 to 2.0 mm from the target site, and Smith & Nephew does not contend that it does.

The Pao '499 Patent does not disclose, as discussed above, a return electrode that is not in contact with the body structure, and Smith & Nephew does not contend that it does. The Pao '499 Patent also does not disclose that an active electrode, return electrode, target site, and tissue structure are immersed in electrically conducting fluid, and Smith & Nephew does not contend that it does. The Pao '499 Patent also does not disclose an electrically conductive fluid that completes the conduction path between the electrode terminal and a return electrode, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose that an electrical current flows from the active electrode, through the electrically conductive fluid, and to a return electrode.

Reference 32: The Valleylab, Inc., "Surgistat Service Manual," does not disclose or render obvious any of the claimed inventions. The Surgistat Service manual only discloses a monopolar system with a patient plate. Smith & Nephew concedes that this reference discloses none of the limitations of the asserted claims of the '536 patent, except a voltage range from 10 volts (RMS) to 1000 volts (RMS). Smith & Nephew also concedes that this reference discloses none of the limitations of the asserted claims of the '882 patent, except a minimum voltage of 200 volts peak to peak and a range from 500 to 1400 volts peak to peak. Smith & Nephew concedes that this reference discloses none of the limitations of the asserted claims of the '592 patent, except a range from 500 to 1400 volts peak to peak.

Reference 34: The article entitled "Radio Frequency and Impedance Feedback" by Paul C. Nardella, which was disclosed during the prosecution of the patents-in-suit, does not disclose or render obvious any of the claimed inventions. As can be seen in Figure 2, and as described on pages 42 and 43, all of the electrical current passes through the tissue before it travels to a return electrode. In addition, the Nardella article states that the active electrode is in contact with the tissue to be treated on pages 42 and 43. The Nardella article also does not disclose directing electrically conductive fluid to the target site. As such, the Nardella article does not disclose that current flows from the active electrode through the electrically conducting fluid to a return electrode. In addition, the Nardella article does not disclose that the voltage applied between the electrode terminal and a return electrode is in the range from 10 volts (RMS) to 1000 volts (RMS), and Smith & Nephew does not contend that it does.

The Nardella article does not disclose a high frequency voltage sufficient to vaporize the fluid over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer. Moreover, the Nardella article does not disclose that at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum. In addition, the Nardella article does not disclose that the voltage applied is at least 200 volts peak to peak or that it is in the range from about 500 to 1400 volts peak to peak, and Smith & Nephew does not contend that it does. The Nardella article does not disclose that the distance between the proximal portion of the electrode terminal and most distal portion of a return electrode is in the range from about 0.5 to 10 mm, and Smith & Nephew does not contend that it does. Moreover, the Nardella article does not disclose that the liquid phase of the fluid has a conductivity greater than 2 mS/cm nor that the fluid comprises isotonic saline, and Smith & Nephew does not contend that it does.

The Nardella article does not disclose ablation of tissue, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal. Moreover, this reference does not disclose the discharge of photons to the target site in contact with a vapor layer. The Nardella article does not disclose that the electrode terminal has a contact surface area in the range of about 0.25 mm^2 to 50 mm^2, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose that the electrode terminal is positioned between 0.02 to 2.0 mm from the target site, and Smith & Nephew does not contend that it does. Moreover, the Nardella article does not disclose evacuating fluid generated at the target site with a

suction lumen having a distal end adjacent the electrode terminal, and Smith & Nephew does not contend that it does.

The Nardella article does not disclose delivering an electrically conductive fluid to the target site, and Smith & Nephew does not contend that it does. The Nardella article also does not disclose that an electrically conductive fluid completes the conduction path between the electrode terminal and a return electrode, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose that an electrical current flows from the active electrode, through the electrically conductive fluid, and to a return electrode.

Reference 36: U.S. Patent No. 4,805,616 to Pao neither discloses nor renders obvious any of the asserted claims of the ArthroCare patents-in-suit. The Pao '616 Patent describes a bipolar probe that is very different than the inventions claimed in the '536, '882, and '592 patents. There is no teaching or suggestion in the Pao '616 Patent that electrically conductive fluid creates a current flow path between the two electrodes. To the contrary, the Pao '616 Patent teaches away from such a path, because it states that both electrodes are brought into contact with the tissue to be treated and that current flows through the tissue between the electrodes -- not through electrically conductive fluid (column 7 lines 33-37). The Pao '616 Patent does not teach that fluid is used for current conduction, but instead for the different purposes of removing blood, other fluid, and debris from the surgical site (see Pao '499 Patent, incorporated by reference, column 3 lines 2-10 and column 8 line 66 to column 9 line 2).

The Pao '616 Patent does not disclose that a return electrode forms a portion of the shaft of the electrosurgical probe, and Smith & Nephew does not contend

that it does. The Pao '616 Patent also does not disclose a return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between a return electrode and the patient's tissue. Moreover, the Pao '616 Patent does not disclose that the frequency applied between a return electrode and the electrode terminal is in the range of about 20 kHz and 20 Mhz, and Smith & Nephew does not contend that it does. The Pao '616 Patent does not disclose that a return electrode is spaced from the electrode terminal to minimize contact between a return electrode and the patient's tissue because a return electrode is designed to be in contact with the tissue. In addition, the Pao '616 Patent does not disclose that the voltage applied between the electrode terminal and a return electrode is in the range from 10 volts (RMS) to 1000 volts (RMS), and Smith & Nephew does not contend that it does.

The Pao '616 Patent does not disclose a high frequency voltage sufficient to vaporize the fluid over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer. Moreover, the Pao '616 Patent does not disclose that at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum. In addition, the Pao '616 Patent does not disclose that the voltage applied is at least 200 volts peak to peak or that it is in the range from about 500 to 1400 volts peak to peak, and Smith & Nephew does not contend that it does.

The Pao '616 Patent does not disclose ablation of tissue, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal. Moreover, this reference does not disclose the discharge of photons

to the target site in contact with a vapor layer. The Pao '616 Patent does not disclose that the electrode terminal has a contact surface area in the range of about 0.25 mm^2 to 50 mm^2. In addition, this reference does not disclose that the electrode terminal is positioned between 0.02 to 2.0 mm from the target site, and Smith & Nephew does not contend that it does. Moreover, the Pao '616 Patent does not disclose evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal, and Smith & Nephew does not contend that it does.

The Pao '616 Patent does not disclose, as discussed above, a return electrode that is not in contact with the body structure, and Smith & Nephew does not contend that it does. The Pao '616 Patent also does not disclose that an active electrode, return electrode, target site, and tissue structure are immersed in electrically conducting fluid. The Pao '616 Patent also does not disclose delivering the electrically conductive fluid to the target site. The Pao '616 Patent also does not disclose an electrically conductive fluid that completes the conduction path between the electrode terminal and a return electrode, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose that an electrical current flows from the active electrode, through the electrically conductive fluid, and to a return electrode.

Reference 38: The article entitled "Thermal Compression and Molding Atherosclerotic Vascular Tissue With Use of Radiofrequency Energy: Implications for Radiofrequency Balloon Angioplasty," by Benjamin Lee, et al., does not disclose or render obvious any of the claimed inventions. Among other things, the Lee article does not disclose a return electrode and instead discloses the use of a "copper electrode plate" (see page 1168). The Lee article also teaches that all of the electrical current passes

through the tissue and does not disclose that an electrically conductive fluid completes a current flow path between an active electrode and a return electrode (page 1168).

The Lee article does not disclose that a return electrode forms a portion of the shaft of the electrosurgical probe, and Smith & Nephew does not contend that it does. The Lee article also does not disclose an insulating member circumscribing a return electrode. In addition, the Lee article does not disclose that the frequency applied between a return electrode and the electrode terminal is in the range of about 20 kHz and 20 Mhz, and Smith & Nephew does not contend that it does. The Lee article does not disclose that a return electrode is spaced from the electrode terminal to minimize contact between a return electrode and the patient's tissue. In addition, the Lee article does not disclose that the voltage applied between the electrode terminal and a return electrode is in the range from 10 volts (RMS) to 1000 volts (RMS), and Smith & Nephew does not contend that it does.

The Lee article does not disclose a high frequency voltage sufficient to vaporize the fluid over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer. Moreover, the Lee article does not disclose that at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum. In addition, the Lee article does not disclose that the voltage applied is at least 200 volts peak to peak or that it is in the range from about 500 to 1400 volts peak to peak, and Smith & Nephew does not contend that it does. The Lee article does not disclose that the distance between the proximal portion of the electrode terminal and most distal portion of a return electrode is in the range from about 0.5 to 10 mm, and Smith & Nephew does not contend that it does.

The Lee article does not disclose ablation of tissue, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal. Moreover, this reference does not disclose the discharge of photons to the target site in contact with a vapor layer. In addition, this reference does not disclose that the electrode terminal is positioned between 0.02 to 2.0 mm from the target site, and Smith & Nephew does not contend that it does. Moreover, the Lee article does not disclose evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal, and Smith & Nephew does not contend that it does.

The Lee article does not disclose, as discussed above, a return electrode that is not in contact with the body structure, and as such does not disclose positioning a return electrode within the volume of electrically conductive fluid to generate the current flow path between the electrode terminal and a return electrode. The Lee article also does not disclose that an active electrode, return electrode, target site, and tissue structure are immersed in electrically conducting fluid. The Lee article also does not disclose an electrically conductive fluid that completes the conduction path between the electrode terminal and a return electrode, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose that an electrical current flows from the active electrode, through the electrically conductive fluid, and to a return electrode.

Reference 48: U.S. Patent No. 4,976,711 to Parins, et al., does not disclose or render obvious any of the claimed inventions. Parins '711 Patent discloses a catheter for removing stenotic lesions from seriously blocked blood vessels. Parins '711 Patent does not disclose a return electrode but instead two active electrodes that are put in

contact with the tissue. This reference also does not disclose the use of electrically conductive fluid to complete a current flow path between an active and return, and instead teaches that an arc is formed when the active and return electrode "are pushed up against the lesion" (column 4 lines 33-38, column 5 lines 24-26, 6 lines 20-25, column 7 lines 8-11). As such, the Parins '711 Patent does not disclose a return electrode which is designed to reduce tissue effect. Although Parins discusses a "flush lumen," Parins discloses the use of a saline solution only for "flushing or aspirating the wound site" and not for conducting electrical current (column 6 lines 26-27, column 7 lines 15-18).

The Parins '711 Patent does not disclose that the frequency applied between a return electrode and the electrode terminal is in the range of about 20 kHz and 20 Mhz, and Smith & Nephew does not contend that it does. The Parins '711 Patent does not disclose that a return electrode is spaced from the electrode terminal to minimize contact between a return electrode and the patient's tissue because a return electrode is designed to be in contact with the tissue. In addition, the Parins '711 Patent does not disclose that the voltage applied between the electrode terminal and a return electrode is in the range from 10 volts (RMS) to 1000 volts (RMS), and Smith & Nephew does not contend that it does. Smith & Nephew also does not contend that this reference discloses a device for use on a target site selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

The Parins '711 Patent does not disclose a high frequency voltage sufficient to vaporize the fluid over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

Moreover, the Parins '711 Patent does not disclose that at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum. In addition, the Parins '711 Patent does not disclose that the voltage applied is at least 200 volts peak to peak or that it is in the range from about 500 to 1400 volts peak to peak, and Smith & Nephew does not contend that it does. The Parins '711 Patent does not disclose that the distance between the proximal portion of the electrode terminal and most distal portion of a return electrode is in the range from about 0.5 to 10 mm, and Smith & Nephew does not contend that it does.

In addition, this reference does not disclose vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal. Moreover, this reference does not disclose the discharge of photons to the target site in contact with a vapor layer. The Parins '711 Patent does not disclose that the electrode terminal has a contact surface area in the range of about 0.25 mm^2 to 50 mm^2, and Smith & Nephew does not contend that it does. In addition, this reference does not disclose that the electrode terminal is positioned between 0.02 to 2.0 mm from the target site, and Smith & Nephew does not contend that it does.

The Parins '711 Patent does not disclose, as discussed above, a return electrode that is not in contact with the body structure. The Parins '711 Patent also does not disclose that an active electrode, return electrode, target site, and tissue structure are immersed in electrically conducting fluid. The Parins '711 Patent also does not disclose an electrically conductive fluid that completes the conduction path between the electrode terminal and a return electrode. In addition, this reference does not disclose that an

electrical current flows from the active electrode, through the electrically conductive fluid, and to a return electrode.

Reference 51: U.S. Patent No. 5,007,908 to Rydell, which was disclosed during the prosecution of the '592 patent-in-suit, does not disclose or render obvious any of the claimed inventions. Rydell '908 depicts a bipolar surgical instrument for use in performing surgery in the gastrointestinal tract (column 1 lines 9-12). Each of the electrodes of the Rydell '908 device is brought into contact with the tissue to be treated (column 1 line 63 to column 2 line 2). Rydell '908 also describes that one may introduce saline or other suitable solution to flush away blood, body fluids, and other debris to improve viewing of the surgical site (column 3 lines 53-57).

The Rydell '908 patent never states that electrically conducting fluid creates a current flow path between the electrodes. To the contrary, the Rydell '908 patent teaches that the purpose of the fluid is to wash the surgical site free of blood, other body fluids, and debris. It also teaches that both electrodes are in contact with the tissue, which suggests that the current flow path is through the tissue, as is customary in conventional bipolar electrosurgery, rather than through the electrically conducting fluid.

The Rydell '908 patent emphasizes that the active electrode and a return electrode are placed in contact with the tissue, and as such it does not disclose that the electrically conducting fluid generates a current flow path between a return electrode and the electrode terminal. In addition, Rydell '908 does not disclose that a return electrode is spaced away from the tissue. Moreover, because the function of the fluid is to flush the region free of blood, body fluids, and other debris, there is no assurance that the active or return electrodes operate in the presence of electrically conducting fluid, because the

fluid may disperse from the area after flushing. This is different than, for example, arthroscopic surgery, in which the fluid is used to distend the joint and the tissue is thus always submerged under water. The Rydell '908 Patent also does not disclose that the voltage applied between a return electrode and the electrode terminal is in the range of about 20 kHz and 20 Mhz. In addition, the Rydell '908 Patent does not disclose that the voltage applied between the electrode terminal and a return electrode is in the range from about 10 volts (RMS) to 1000 volts (RMS).

Rydell '908 patent does not disclose the voltage sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal, or the discharge of energy to the target site. The Rydell '908 patent also does not disclose that at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum, and Smith & Nephew does not contend that it does. The Rydell '908 patent does not disclose the voltage at which the device operates, and certainly does not disclose that that voltage is at least 200 volts peak to peak or that it is in the range from 500 to 1400 volts peak to peak, and Smith & Nephew does not contend that it does. The Rydell '908 patent does not disclose that the distance between the most proximal portion of the electrode terminal and most distal portion of a return electrode is in the range from about 0.5 to 10 mm, and Smith & Nephew does not contend that it does.

The Rydell '908 Patent does not disclose the ablation of tissue, but merely describes cutting tissue, and Smith & Nephew does not contend that it does. In addition, Rydell '908 Patent does not disclose vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal. Moreover, Rydell '908 Patent does not disclose the discharge of photons to the target site in contact with a vapor layer, and

Smith & Nephew does not contend that it does. Rydell '908 Patent does not disclose that the electrode terminal has a contact surface area in the range of about 0.25 mm^2 to 50 mm^2, and Smith & Nephew does not contend that it does. In addition, Rydell '908 Patent does not disclose that the electrode terminal is positioned between 0.02 to 2.0 mm from the target site, and Smith & Nephew does not contend that it does. Moreover, Rydell '908 Patent does not disclose evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal, and Smith & Nephew does not contend that it does.

The Rydell '908 Patent does not disclose that an electrically conductive fluid completes the conduction path between the electrode terminal and a return electrode. In addition, the Rydell '908 Patent does not disclose that an electrical current flows from the active electrode, through the electrically conductive fluid, and to a return electrode. Moreover, the Rydell '908 Patent does not disclose that an active electrode, return electrode, target site, and tissue structure are immersed in electrically conducting fluid. To the contrary, the '908 patent teaches that the fluid is introduced to "flush" or "wash" the target site.

Reference 52: U.S. Patent No. 5,009,656 to Reimels ("Reimels '656"), which was disclosed during the prosecution of the '882 and '592 patents-in-suit, does not anticipate or render obvious any of the claimed inventions.

Reimels '656 describes a device having a pair of electrodes adjacent to each other that are brought into contact with the tissue to be cut or coagulated (figure 2 and column 4 lines 12-15). An "air gap" is formed at the tip of the device between the inner electrode and the outer electrode by removing some of the insulation between the

electrode pair (figure 2 and column 4 lines 12-15). Reimels '656 states that fluid, such as saline, is dispelled from the air gap and that current flows in "sparks" between the electrodes across the air gap (column 4 lines 3-11). Because Reimels '656 states that the inner electrode and the outer electrode are placed in contact with the tissue, and because it states that saline is dispelled from the "air gap" between the two electrodes, Reimels '656 does not suggest how to successfully use the device in electrically conducting fluid, with the fluid being the conduit for electrical current between an active electrode and a return electrode.

The Reimels '656 patent never states that electrically conducting fluid creates a current flow path between the electrodes. To the contrary, the Reimels '656 patent teaches that the electrodes are in contact with the tissue, the electrically conducting fluid is dispelled from the area between the electrodes, and that current flows in the form of "sparks" across an "air gap" between the electrodes, not through electrically conducting fluid (column 4 lines 3-11).

The Reimels '656 patent states that the electrodes are placed in contact with the tissue, and as such it does not disclose that the electrically conducting fluid generates a current flow path between a return electrode and the electrode terminal. In addition, Reimels '656 does not disclose that a return electrode is spaced away from the tissue, and Smith & Nephew does not contend that it does. The Reimels '656 Patent also does not disclose that the voltage applied between a return electrode and the electrode terminal is in the range of about 20 kHz and 20 Mhz, and Smith & Nephew does not contend that it does. In addition, the Reimels '656 Patent does not disclose that the voltage applied between the electrode terminal and a return electrode is in the range from

about 10 volts (RMS) to 1000 volts (RMS), and Smith & Nephew does not contend that it does.

The Reimels '656 patent also does not disclose that at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum. The Reimels '656 patent does not disclose the voltage at which the device operates, and certainly does not disclose that that voltage is at least 200 volts peak to peak or that it is in the range from 500 to 1400 volts peak to peak, and Smith & Nephew does not contend that it does. The Reimels '656 patent does not disclose that the distance between the most proximal portion of the electrode terminal and most distal portion of a return electrode is in the range from about 0.5 to 10 mm, and Smith & Nephew does not contend that it does.

The Reimels '656 Patent does not disclose the ablation of tissue, and Smith & Nephew does not contend that it does. Moreover, Reimels '656 Patent does not disclose the discharge of photons to the target site in contact with a vapor layer. Reimels '656 Patent does not disclose that the electrode terminal has a contact surface area in the range of about 0.25 mm^2 to 50 mm^2, and Smith & Nephew does not contend that it does. In addition, Reimels '656 Patent does not disclose that the electrode terminal is positioned between 0.02 to 2.0 mm from the target site, and Smith & Nephew does not contend that it does. Moreover, Reimels '656 Patent does not disclose evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal, and Smith & Nephew does not contend that it does.

The Reimels '656 Patent does not disclose that an electrically conductive fluid completes the conduction path between the electrode terminal and a return

electrode. In addition, the Reimels '656 Patent does not disclose that an electrical current flows from the active electrode, through the electrically conductive fluid, and to a return electrode.

Reference 74: The CMC-III Bipolar System, attributed to Malis, does not disclose or render obvious any of the claimed inventions. As an initial matter, the Malis materials are not a single reference, but are instead a collection of documents, many of which are undated. As such, it appears that the materials are not prior art. For those that are dated, they are after the effective filing dates of the patents-in-suit.

Both of the electrodes in the Malis materials are in contact with the tissue and create a current flow path between them. The materials state that there is no current flow path through the saline, but instead that all current goes between the forceps through the tissue (SN61176, SN61178, fig. 14, SN61179). As such, the Malis materials do not show a current flow path between active and return electrodes through an electrically conducting fluid. In fact, Malis says opposite: there is no current flow other than through the tissue that is being grasped by the two electrodes. Another distinction between the Malis materials and the claimed inventions is that the device described in the Malis materials uses a biactive approach in which each electrode is of equal size and both are used to treat tissue. As such, Malis does not disclose a return electrode which is designed not to cause a tissue effect and which has a current density lower than the other electrode because Malis discloses a biactive device in which both electrodes are designed to cause a tissue effect (SN61173).

The Malis materials do not disclose that the frequency applied between a return electrode and the electrode terminal is in the range of about 20 kHz and 20 Mhz.

The Malis materials do not disclose that a return electrode is spaced from the electrode terminal to minimize contact between a return electrode and the patient's tissue because a return electrode is designed to be in contact with the tissue. In addition, the Malis materials do not disclose that the voltage applied between the electrode terminal and a return electrode is in the range from 10 volts (RMS) to 1000 volts (RMS). The Malis materials also do not disclose a device for use on a target site selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

The Malis materials do not disclose a high frequency voltage sufficient to vaporize the fluid over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer. Moreover, the Malis materials do not disclose that at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum. In addition, the Malis materials do not disclose that the voltage applied is at least 200 volts peak to peak or that it is in the range from about 500 to 1400 volts peak to peak. The Malis materials do not disclose that the distance between the proximal portion of the electrode terminal and most distal portion of a return electrode is in the range from about 0.5 to 10 mm.

The Malis materials do not disclose ablation of tissue. In addition, the Malis materials do not disclose vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal. Moreover, the Malis materials do not disclose the discharge of photons to the target site in contact with a vapor layer. The Malis materials do not disclose that the electrode terminal has a contact surface area in the range of about 0.25 mm^2 to 50 mm^2. In addition, the Malis materials do not disclose

that the electrode terminal is positioned between 0.02 to 2.0 mm from the target site. Moreover, the Malis materials do not disclose evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

The Malis materials do not disclose, as discussed above, a return electrode that is not in contact with the body structure. The Malis materials do not disclose that an active electrode, return electrode, target site, and tissue structure are immersed in electrically conducting fluid. In addition, the Malis materials do not disclose that an electrically conductive fluid completes the conduction path between the electrode terminal and a return electrode. Moreover, the Malis materials do not disclose that an electrical current flows from the active electrode, through the electrically conductive fluid, and to a return electrode.

II. Nonobviousness

ArthroCare objects to providing its contentions as to nonobviousness on the grounds that Smith & Nephew has failed to state a prima facie case that the patents-in-suit may be invalid for obviousness. Smith & Nephew has not articulated any motivation to combine any of the references it is asserting, other than to state that "each reference is directed to the same problem – applying electrical energy to the target site on a patient's body." As a matter of law this is not a motivation to combine. If it were, then any electrosurgical reference, regardless of content and regardless of its teaching, would be combined by a person having ordinary skill in the art with any other reference, regardless of its content or teaching. The absurdity of this result demonstrates that Smith & Nephew has shown no motivation to combine.

In addition, the combinations of references on which Smith & Nephew intends to rely are hopelessly overbroad. For example, Smith & Nephew contends that

Claim 46 of the '536 patent is rendered invalid for obviousness based on the combination of "any one or more of" five references in combination "with any one or more of" eight other references, which results in literally thousands of combinations. As such, ArthroCare is unable to provide a response to the vast array of possible combinations identified by Smith & Nephew.

To the extent that Smith & Nephew at a later time seeks to argue that any of the claims of patents-in-suit are obvious, and makes prima facie case, then ArthroCare reserves the right to argue that any of the references alone or in combination do not render any claims of the patents-in-suit obvious. In doing so, ArthroCare reserves the right to rely on secondary indicia nonobviousness, including arguments based on (a) commercial success of ArthroCare's products that embody one or more claims of the patent-in-suit, (see ARTC 63370-63535, ARTC 64624-64627, ARTC 63926-64181, ARTC 23416-24808, ARTC 25247-27009, ARTC 27937-28855, ARTC 29888-31317, ARTC 31492-34642, ARTC 63608-63619, ARTC 63656-63809, and the transcripts and exhibits from the depositions of John Tighe, Christine Hanni, Fernando Sanchez, Al Weinstein, Michael Baker, and John Raffle in this case); (b) industry acquiescence and acknowledgement of the strength of the patents-in-suit (SN 54891, ORA 0000082, ORA 57060-62, SN 57688-695, ARTC 20679-20731, ARTC 7783-7789, ARTC 7743-7782, ARTC 13955-13964, ARTC 59948-60008, ARTC 25247-27009, ARTC 27937-28222, ARTC 30695-31026, ARTC 31492-32604, ARTC 34148-34642, and the transcripts and exhibits from the depositions of Christine Hanni, Fernando Sanchez, Michael Baker, and John Raffle in this case); (c) evidence that Smith & Nephew has copied ArthroCare's patented technology (ORA 7298-7304, ORA 7734-7961, ORA 50522-525, ORA 8033-

34, ORA 9221, ORA 971-975, ORA 9153, SN 19618, SN 19659-60, SN 20312, SN 21884, SN 29781, SN 34455, SN 36073, and the transcripts and exhibits to the depositions of Duane Marion, Kate Knudsen, Linda Guthrie, Sally Maher, and John Konsin).